K103633

MAY 11 2011

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December, 10th, 2010
Submitter:	GE Healthcare (GE Medical Systems (China) Co., Ltd) No.19, Changjiang Road, Wuxi National Hi-Tech Development Zone, Jiangsu, China
Primary Contact Person:	Chris Paulik Regulatory Affairs Leader GE Healthcare Phone: 262-548-2010 Fax: 262-546-0704
Secondary Contact Person:	Dave Blonski RA Director GE Healthcare Phone: 262-513-4072 Fax: 262-997-1160
Device: Trade Name:	Achilles
Common/Usual Name:	Achilles EXPII
Classification Names:	21CFR892.1180, Class II
Product Code:	MUA
Predicate Device:	P970040/S001 Achilles Express Ultrasonometer
Device Description:	Achilles EXPII measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index. The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip. Detail descriptions are included in section 11.
Intended Use:	The Achilles ultrasonometer measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index. The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip. Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by x-ray absorpiometry. Either the stiffness index t-score or x-ray absorptiometry t-score can be utilized by a

physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment.

The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.

Technology: The Achilles EXPII employs the same fundamental scientific technology as its predicate(s).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Achilles EXPII Bone sonometer and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

A clinical study GE3120 was performed to determine the precision of the Achilles EXPII Bone sonometer and the correlation of the results for the Achilles EXPII and the Achilles Express. See section 20 of this premarket submission.

Stiffness Index results obtained from the Achilles EXPII was shown to be equivalent to those obtained by the Achilles Express *in vivo*. Linear regression of Stiffness Index values from the two devices demonstrated high correlation (R=0.97)

Comparison of Stiffness values demonstrated no significant differences.

See section 20 of this premarket submission.

Conclusion: GE Healthcare considers the Achilles EXPII to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Chris Paulik
Regulatory Affairs Leader
GE Medical Systems China Co., Ltd.
No. 19 Changhiang Road National Hi-Tech Dev. Zone
Wuxi, Jiangsu 214028
CHINA

MAY 1 1 2011

Re: K103633
Trade/Device Name: Achilles EXPII Bone Sonometer
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone sonometer
Regulatory Class: II
Product Code: MUA
Dated: December 10.2010
Received: March 3, 2011

Dear Mr. Paulik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Achilles EXPII Bone Sonometer

Indications for Use:

The Achilles ultrasonometer measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index. The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip.

Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by x-ray absorpiometry. Either the stiffness index t-score or x-ray absorptiometry t-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment.

The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.

Prescription Use_X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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